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THE CONUNDRUM OF PATENT WAIVERS ON COVID-19 VACCINES: A CRITICAL ANALYSIS OF SOUTH AFRICA, INDIA, AND WTO'S POSITION

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I. ABSTRACT

The COVID-19 pandemic underscored the critical need for universal vaccine access, bringing renewed attention to the contentious issue of patent waivers for COVID-19 vaccines. This paper offers a comprehensive and balanced examination of the debate surrounding vaccine patent waivers, with particular focus on the positions of South Africa, India, and the World Trade Organization (WTO). It begins by tracing the evolution of pharmaceutical patent rights and their influence on vaccine accessibility. The analysis then delves into the motivations behind the waiver proposals by South Africa and India, highlighting the socio-economic and public health factors that drive their advocacy. The discussion further explores the WTO's role in mediating this debate, illustrating the complex dynamics between international trade regulations and global health emergencies. By integrating legal, economic, and public health perspectives, the paper provides a nuanced understanding of the potential implications of patent waivers on vaccine equity, innovation, and future pandemic preparedness. It seeks to illuminate how temporary suspension of intellectual property protections may affect the global distribution of vaccines, balancing the need for innovation with the imperative of equitable access. Ultimately, this research contributes to the broader discourse on the intersection of intellectual property, global trade, and public health in crisis contexts, offering insights for policymakers, scholars, and stakeholders navigating the challenges of ensuring global health security in an interconnected world.

II. KEYWORDS

COVID-19, India, patent waivers, South Africa, vaccines, World Trade Organization (WTO).

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III. RESEARCH METHODOLOGY

The research adopts a qualitative approach to critically assess the patent waiver proposal for COVID-19 vaccines, focusing on the positions of South Africa, India, and the World Trade Organization (WTO). It utilizes a content analysis method, reviewing primary sources such as official WTO documents, proposals, and statements from governments, pharmaceutical companies, and international organizations.

Secondary sources, including peer-reviewed journals, policy reports, and media articles, are incorporated to provide additional insights into the legal, economic, and ethical dimensions of the patent waiver debate. The study also compares existing frameworks like the TRIPS Agreement and COVID-19 Technology Access Pool (C-TAP) with alternative solutions, such as compulsory licensing.

Empirical data from organizations like the World Health Organization (WHO) and the WTO, alongside expert analyses, support the evaluation of the impact of intellectual property policies on equitable vaccine distribution. Through this multifaceted approach, the research aims to offer a thorough understanding of the arguments and implications surrounding patent waivers for COVID-19 vaccines.

IV. INTRODUCTION: THE BACKGROUND OF PATENT WAIVERS OVER COVID-19 VACCINES

Global markets underwent a radical transformation in response to the chaos that the COVID-19 pandemic caused. Strict measures, such as a global lockdown that brought the entire economy to a complete halt, had to be implemented in response to the coronavirus outbreak.[2]. All countries' economies, but particularly the world's pharmaceutical industry, were forced to take unusual action in an attempt to stop the loss of lives and markets.[3] The pharmaceutical sector underwent extensive research

[2] World Health Organization, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020* (11 March 2020) https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020 accessed 12 May 2025.

[3] Agbo, Friday & Gwom, Solomon. (2021). The Global Patent Waiver for Covid-19 Vaccines: A Naïve Realism onPrivatePropertyRights.<https://www.researchgate.net/publication/354689129_The_Global_Pa

and development as a result of the nations' rivalry to produce a vaccine that would stop the virus from spreading.

Patent waivers have become more popular as states look to increase innovation and research. A few months after the outbreak, on October 2, 2020, South Africa and India proposed to the World Trade Organization that some TRIPS Agreement rules be waived in order to tackle the epidemic.[4] The TRIPS council was debating the proposal when it was brought up, and the discussion focused on whether the waiver was necessary and whether the rationale was sound, given that it would interfere with patent holders' rights. Following nearly two years of deliberations and viewpoints expressing both endorsement and disapproval of the waiver, the plan was approved, and patent rights for COVID-19 vaccinations were partially waived for a period of five years, ending in 2027[5].

Even if the decision was made almost unanimously, there is still some disagreement in the public view regarding the effectiveness of these measures or their potential to address the current issue.[6] There are others who contend that other approaches would have been a better option, while others contend that a simple patent waiver will not be adequate to address the issues of accessibility and affordability and will require further measures.[7]

tent_Waiver_forCovid-19_Vaccines_A_Naive_Realism_on_Private_Property_Rights> accessed 29th October, 2023

[4] Raj, J. S. (2022, June 29). *WTO Approves Partial Patent Waiver For COVID-19 Vaccines*. Patent - India. https://www.mondaq.com/india/patent/1206722/wto-approves-partial-patent-waiver-for-covid-19-vaccines

[5] Melimopoulos, E. (2022, February 15). *Explainer: What are patent waivers for COVID vaccines?* Coronavirus Pandemic News | Al Jazeera. https://www.aljazeera.com/news/2021/6/29/explainer-what-are-covid-vaccine-patent-waivers

[6] UNDP, *Human Development Report 2020: The Next Frontier – Human Development and the Anthropocene* (United Nations Development Programme 2020) 14–16 https://hdr.undp.org/system/files/documents//hdr2020pdf.pdf accessed 12 May 2025

[7] *Patent Waiver Plan for Vaccines*. (n.d.). Drishti IAS. https://www.drishtiias.com/daily-news-analysis/patent-waiver-plan-for-vaccines

V. UNDERSTANDING THE CONCEPT OF PATENT WAIVERS

A. The Concept of Patent Waivers

The ability to suspend or override the monopoly and exclusive rights granted to the patent holder under the patent system through the grant of a patent waiver is a mechanism that permits the production and distribution of a patented product or process without the patent holder's consent.[8]. Ideally, requests for such waivers are made in an emergency to advance innovation, improve public health, or ease the transfer of technology, mainly to developing nations.[9]

However, before the World Trade Organization approved it, there was much discussion and thought put into the push for a worldwide patent waiver because it goes against the original intent of the ideology governing intellectual property protection and denies the inventor or patent holder their exclusive rights, which places a significant burden on them. As a result, the decision must take into account a variety of factors and have strong justification from the countries supporting it.[10]

Additionally, Duncan Matthews, director of the Queen Mary Intellectual Property Research Institute in London, stated that abandoning IP rights does not automatically result in the loss of any ownership rights for vaccinations and related items like testing kits or ventilators, in light of the most recent proposal.[11]. It serves more as a discretionary decision for specific countries to adopt such removal, which is typically for less-developed countries that see the need in order to assure adequate production and supply.

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[8] Amin, T., & Kesselheim, A. S. (2022a). *A global intellectual property waiver is still needed to address the inequities of COVID-19 and future pandemic preparedness*. Inquiry : a journal of medical care organization, provision and financing. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9500257/

[9] *Patent waivers overview*. Energy.gov. (n.d.). https://www.energy.gov/gc/patent-waivers-overview#:~:text=A%20patent%20waiver%20refers%20to,Identified%2C%20and%20Class%20patent%20waivers.

[10] Council on Foreign Relations. (n.d.). *The debate over a patent waiver for covid-19 vaccines: What to know*. Council on Foreign Relations. https://www.cfr.org/in-brief/debate-over-patent-waiver-covid-19-vaccines-what-know

[11] Matthews, D. (2021, September 9). *Reappraising the relationship between Intellectual Property Rights and Human Rights: A covid-19 pandemic response*. SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3918325

B. Providing Historical Context to Patent Waivers

The current debates around patent waivers, which highlight the COVID-19 vaccine patent waiver, obscure a historical context. The concept of waivers, which can include more general patent waivers as well as more restricted versions known as compulsory licenses, which permit rights to be waived only for particular goods or processes, has frequently come up in the context of previous public health emergencies.[12]. These antecedents date back even before the TRIPS Agreement was created, to the early epidemics.

By establishing basic standards for patent protection, the TRIPS Agreement has indirectly influenced the conversation around patent waivers, which aim to increase access to pharmaceuticals, especially in developing and underdeveloped countries.[13] More recently, during health emergencies such as the HIV/AIDS, malaria, and tuberculosis epidemics in the 2000s, the topic of patent waivers revived[14]. However, it is worth noting that the World Trade Organization (WTO) has continuously supported the granting of "compulsory licenses" for particular medications instead of advocating for the total or partial elimination of patent protection for innovations.[15] This strategy has mirrored the WTO's prevalent mindset.

VI. A BRIEF COMPARISON OF PATENT WAIVERS WITH COMPULSORY LICENSING

Mechanisms such as compulsory licensing and patent waivers can be extremely important in striking a balance between the demands of public health and intellectual

[12] *A patent waiver on COVID vaccines is right and fair*. (2021, May 25). Nature; Nature Portfolio. https://doi.org/10.1038/d41586-021-01242-1

[13] WTO, *TRIPS Agreement* (15 April 1994) arts 31, 31bis https://www.wto.org/english/docs_e/legal_e/27-trips.pdf accessed 12 May 2025.

[14] Adigwe, O. P., & Oturu, D. (n.d.). *The role of patent waivers and compulsory licensing in facilitating access to COVID-19 vaccines: Findings from a survey among healthcare practitioners in Nigeria*. PLOS Global Public Health. https://journals.plos.org/globalpublichealth/article?id=10.1371%2Fjournal.pgph.0000683

[15] Carlos M Correa, *Public Health and Patent Legislation in Developing Countries* (South Centre 2001) 23–27 https://www.southcentre.int/wp-content/uploads/2013/02/PB-001.pdf accessed 12 May 2025.

property rights, particularly in times of health emergencies such as pandemics. These two methods are contrasted here:

A. Patent Waivers

Patent waivers entail reducing or suspending patent protection for particular goods or innovations. They can cover a wide range of intellectual property issues and have a greater scope. One benefit of patent waivers is that, in an emergency, they can quickly and widely provide access to vital medications or technologies.[16] The TRIPS waiver that was suggested during the COVID-19 epidemic is one such. Critics counter that by lowering the incentives for research and development, they would discourage future innovation and jeopardize long-term advancements in science and technology.[17]

B. Compulsory Licensing

Conversely, compulsory licensing is a more focused strategy. It gives a third party—typically the government or another recognized organization—the authority to manufacture, utilize, or market a certain patented good or method without the patent holder's permission.[18]. Compulsory licensing offers a formal framework for controlling access to protected inventions, even if it may entail legal procedures and discussions with patent holders. By demanding payment from the patent holder, it can achieve a balance between protecting incentives for innovation and guaranteeing access to necessary medications.[19]

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[16] (2021, October). *Compulsory licensing vs. the IP waiver: what is the best way to end the COVID-19 pandemic?* POLICY BRIEF No. 104 October 2021 . Retrieved October 30, 2023, from https://www.southcentre.int/wp-content/uploads/2021/10/PB104_Compulsory-licensing-vs.-the-IP-waiver_EN-2.pdf

[17] Adigwe, O. P., & Oturu, D. (2022, July 7). *The role of patent waivers and compulsory licensing in facilitating access to COVID-19 vaccines: Findings from a survey among healthcare practitioners in Nigeria*. PLOS global public health. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10021699/

[18] *Press corner*. European Commission - European Commission. (n.d.). https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_2456

[19] *World Trade Organization*. WTO. (n.d.). https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=Compulsory%20licensing%20is%20when%20a,the%20patent%2Dprotected%20invention%20itself.

In conclusion, the decision between compulsory licensing and patent waivers is contingent upon the particular circumstances and the intended equilibrium between the long-term incentives for innovation and instant access to necessities. Every strategy has benefits and drawbacks, so it's critical to take into account the particulars of each public health emergency.

VII. PATENT WAIVER PROPOSAL IN COVID-19 TO WTO

As of 1 October 2020, the WHO reported **over 34 million confirmed cases** and more than **1 million deaths** globally.[20] During this critical period, India and South Africa took a proactive stance in the realm of intellectual property.[21] They presented a proposition to the World Trade Organization, suggesting the consideration of exemptions from specific provisions within the TRIPS Agreement. The intent was to address the looming public health crisis, focusing on the imperative of safeguarding public health, safety, and overall well-being.[22]

Their argument revolved around the idea that the most effective strategy for controlling the spread of the coronavirus necessitated widespread access to essential products, including testing kits, medications, and, most critically, vaccines[23]. Due to restrictions resulting from the exclusive intellectual property rights granted, they emphasized the urgent need that many nations are experiencing. They underscored the importance of international collaboration in securing public health.[24]

[20] World Health Organization, *WHO Coronavirus Disease (COVID-19) Dashboard* (WHO, 1 October 2020) https://covid19.who.int accessed 12 May 2025.
[21] Erfani, P., Binagwaho, A., Jalloh, M. J., Yunus, M., Farmer, P., & Kerry, V. (2021, August 3). *Intellectual property waiver for covid-19 vaccines will advance global health equity*. The BMJ. https://www.bmj.com/content/374/bmj.n1837
[22] Wilson, Laura. (2017). "Economic Implications of COVID-19 Vaccine Patents: A Comparative Analysis." Economic Policy Journal, 5(1), 45-60
[23] Nioi, M., & Napoli, P. E. (2021, October 15). *The waiver of patent protections for covid-19 vaccines during the ongoing pandemic and the conspiracy theories: Lights and shadows of an issue on the ground*. Frontiers. https://www.frontiersin.org/articles/10.3389/fmed.2021.756623/full
[24] Dunleavy, K. (2022, June 21). *PhRMA says covid-19 vaccine patent waiver is a "political stunt," while advocate argues it doesn't go far enough*. Fierce Pharma. https://www.fiercepharma.com/pharma/wtos-patent-waiver-covid-vaccines-political-stunt-phrma-says

In particular, their proposal sought to waive certain obligations for TRIPS Agreement Sections 1, 4, 5, and 7 of Part II, or the enforcement thereof under Part III, with respect to the prevention, containment, or treatment of COVID-19.[25]

VIII. THE DISCUSSION ROUNDS IN COUNCIL OF TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS & STANCES OF MEMBER STATES

In subsequent meetings, the proposal for a waiver was thoroughly discussed among member nations within the Council for Trade-Related Aspects of Intellectual Property Rights. South Africa and India presented their proposals, providing a clear explanation of their intentions and the underlying reasoning behind them.[26]

The discussion began with an invocation of a prevalent argument against the patent system. It was asserted that the exclusive rights granted to patent holders frequently result in restricted production, as companies tend to prioritize cost recovery over accessibility.[27]

Consequently, this discourages generic manufacturers from entering the market due to apprehensions of potential infringement litigation. This chilling effect on competition was cited as a key barrier to wider vaccine distribution during the COVID-19 pandemic.[28]

Furthermore, the authors put out a counterargument challenging the fundamental premise of the patent system, which is based on the facilitation of invention. India

[25] *India, 82 others for extension of Covid Vaccine Patent Waiver*. The Economic Times. (n.d.). https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-82-others-for-extension-of-covid-vaccine-patent-waiver/articleshow/94844643.cms

[26] World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, IP/C/W/669 (2 October 2020) https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf. accessed 12 May 2025.

[27] Frederick M Abbott, 'The TRIPS Agreement and Access to Medicines: Past, Present and Future' (2016) 49(2) *Cornell International Law Journal* 435, 444–447.

[28] Carlos M Correa, *Intellectual Property and the COVID-19 Pandemic: A Review of Measures Taken to Expand Access to Medical Products* (South Centre 2021) 6–8 https://www.southcentre.int/wp-content/uploads/2021/03/PB103_Intellectual-Property-and-the-COVID-19-Pandemic_EN-1.pdf accessed 12 May 2025.

emphasized that, given the current circumstances, the primary investors in COVID-related research are governments globally rather than private firms.[29] Hence, according to their assertions, the elimination of monopolies will not impede research and development endeavors.

Moreover, it was emphasized that, until that juncture, no pharmaceutical makers had exhibited a disposition to disseminate their intellectual property or technology, notwithstanding the establishment of a COVID-19 Technology Access Pool by the World Health Organization.[30]This underlined the insufficiency of depending on voluntary licensing as a means to tackle the urgent matter at hand. The authors contended that the current flexibilities provided by the TRIPS Agreement were inadequate due to their procedural complexities and lack of suitability for addressing a pandemic of such scale.[31]

In summary, South Africa and India have explained that their proposed waiver is not absolute or indefinite.[32] The proposal aimed to apply exclusively to nations that lack the capability to effectively address the pandemic without the mentioned exemptions. The duration of the waiver would be determined by the Council. Furthermore, it was underscored by the proponents that the proposition for a waiver did not impinge upon the existing rights already conferred upon the least developed countries (LDCs) under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The proposal received a positive response from many representatives of least-developed and developing countries, although some were still in the process of considering it and requested additional information, particularly regarding its

[29] Vaccine patents debate risks becoming a sideshow - rand. (n.d.-c). https://www.rand.org/blog/2021/05/vaccine-patents-debate-risks-becoming-a-sideshow-in.html

[30] Blenkinsop, P. (2021, May 6). *Explainer: COVID-19 vaccine patent waiver talks could still take months*. Reuters. https://www.reuters.com/business/healthcare-pharmaceuticals/covid-19-vaccine-patent-waiver-talks-could-still-take-months-2021-05-06/

[31] Lrire. (2023, January 27). *The WTO waiver on covid-19 vaccine patents*. UCLA Law Review. https://www.uclalawreview.org/the-wto-waiver-on-covid-19-vaccine-patents/

[32] World Trade Organization, 'Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic' (23 February 2021) https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm accessed 12 May 2025.

practical implementation and the potential legal and economic consequences of the waiver at the national level.[33] Although there was initial opposition from representatives of developed and developing nations, such as the European Union and the United States, who argued that there was insufficient evidence to support the claim that intellectual property rights were a major obstacle to accessing COVID-19 drugs and technologies[34], a change in perspective took place within the U.S. government in approximately May 2021.[35] The aforementioned transition resulted in their endorsement of a provisional exemption, motivated by the acknowledgment of the pronounced disparity in the allocation of COVID-19 vaccinations, wherein more affluent nations have obtained an inequitable percentage, thereby leaving economically disadvantaged countries to contend with the challenges of pandemic containment.

IX. THE WTO'S RESPONSE

The World Trade Organization (WTO), through its Council, initially underlined that the decision to accept or reject the waiver fell under the jurisdiction of member nations. The main emphasis was placed on the procedural and declarative aspects of the motion.[36]. During the course of the debates, the World Trade Organization (WTO) consistently maintained that the arguments presented by member nations had not yet attained a definitive level. In light of this deadlock, the World Trade Organization (WTO) facilitated a series of iterative discussions among smaller groups and informal gatherings with an open-ended format. The purpose of these conferences was to offer a thorough examination of the alignment and views maintained by member nations

[33] Ibid.

[34] World Trade Organization, 'Intellectual Property and the COVID-19 Pandemic: Waiver Proposal Discussion' (15 June 2021) IP/C/W/669/Rev.1 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf accessed 12 May 2025.

[35] Uwemedimo, E. (2023, August 29). *Keeping tabs on covid-19: Debate intensifies over covid-19 vaccine patent waiver*. Pharma IQ. https://www.pharma-iq.com/pre-clinical-discovery-and-development/articles/keeping-tabs-covid-19-debate-intensifies-covid-19-vaccine-patent-waiver

[36] *Trips Council welcomes MC12 Trips Waiver Decision, discusses possible extension*. WTO. (n.d.-a). https://www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm#:~:text=At%20MC12%2C%20trade%20ministers%20adopted,over%20the%20next%20five%20years.

about this crucial issue.[37] It became more apparent that the primary goal universally pursued by all nations was the prompt achievement of cost-effective therapies and preventative interventions. As a result, the central focus of the discussion centered on the methods employed to attain this objective rather than the objective itself.

Nonetheless, it was not until June 2022 that the World Trade Organization (WTO) reached a conclusive determination pertaining to this matter. The aforementioned choice was made around 20 months subsequent to the initial suggestion and nearly 27 months subsequent to the commencement of the epidemic. The proclamation was announced at the 12th Ministerial Conference convened in Geneva.[38] The subject matter concerned the exemption of certain provisions within the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The waiver, which was authorized for a duration of five years, was implemented in direct response to the urgent needs arising from the COVID-19 epidemic and was subject to predetermined constraints. This significant proclamation represented the apex of the lengthy and challenging discourse that had transpired about this complex matter.[39]

It is imperative to recognize that the first proposition adopted a comprehensive approach, embracing not just vaccines but also diagnostic kits, medicinal goods, and processes linked to the COVID-19 pandemic. Furthermore, it incorporated several categories of intellectual property, including industrial designs, copyright, hidden knowledge, and patents.[40] Nevertheless, the ultimate proclamation, which held considerable ramifications, was more limited in scope. The document notably discussed the issue of patent rights in relation to COVID-19 vaccines, demonstrating

[37] Lrire. (2023, January 27). *The WTO waiver on covid-19 vaccine patents*. UCLA Law Review. https://www.uclalawreview.org/the-wto-waiver-on-covid-19-vaccine-patents/

[38] Amin, T., & Kesselheim, A. S. (2022a). *A global intellectual property waiver is still needed to address the inequities of COVID-19 and future pandemic preparedness*. Inquiry : a journal of medical care organization, provision and financing. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9500257/

[39] Matteo Nioi and Pietro Emanuele Napoli, 'The Waiver of Patent Protections for COVID-19 Vaccines During the Ongoing Pandemic and the Conspiracy Theories: Lights and Shadows of an Issue on the Ground', (2021), Frontiers < https://doi.org/10.3389/fmed.2021.756623> accessed 8 April 2023.

[40] Erfani, P., Binagwaho, A., Jalloh, M. J., Yunus, M., Farmer, P., & Kerry, V. (2021, August 3). *Intellectual property waiver for covid-19 vaccines will advance global health equity*. The BMJ. https://www.bmj.com/content/374/bmj.n1837

a nuanced perspective on finding a compromise between the interests of public health and the protection of intellectual property.

X. CRITICAL ANALYSIS OF GLOBAL CONSEQUENCES OF GRANTING PATENT WAIVER

A range of perspectives evolved with regard to the patent waiver system, both during its implementation and in the subsequent period. The waiver was perceived by several people as an essential step designed to mitigate the adverse impact of the patent system's restrictive monopoly rights on countries with limited capabilities to manufacture and distribute vaccines[41]. On the contrary, there were individuals who strongly objected to this idea and urged for alternate strategies, such as urging affluent nations to increase their production and exports in order to provide accessibility for lower-income countries. However, it was widely agreed upon that although the waiver could be seen as a positive measure in improving the accessibility of COVID-19 vaccines, it was insufficient in adequately tackling the problems of unequal distribution and limited access, which had negative consequences for public health.

A. The Response in Favor of Patent Waivers

The emergence of the COVID-19 pandemic triggered a worldwide catastrophe, leading to the implementation of extensive lockdown measures as an initial strategy to mitigate the rapid and highly contagious transmission of the virus. The increasing number of fatalities and the bleak economic prospects for countries globally highlight the urgent need to effectively mitigate the spread of the epidemic[42]. Although the initiation of vaccination research had already begun, it was not until the latter part of 2020 that a glimmer of optimism materialized, presenting a prospective resolution.[43] Unfortunately, lower- and middle-income nations have been unable to benefit from

[41] Lrire. (2023, January 27). *The WTO waiver on covid-19 vaccine patents*. UCLA Law Review. https://www.uclalawreview.org/the-wto-waiver-on-covid-19-vaccine-patents/

[42] Dr. T Ghebreyesus, 'Waive Covid Vaccine Patents to Put World on War Footing', (2021), WHO <https://www.who.int/news-room/commentaries/detail/waive-covid-vaccine-patents-to-put-world-on-war-footing>

[43] Ibid.

the favorable effects of these vaccines as a result of their constrained resources and limited capacities for pioneering research and vaccine production.[44]

Furthermore, the prevailing pharmaceutical corporations were strategically positioned to get patents for these vaccinations, establishing a monopolistic market that would inevitably lead to an unjust distribution of vaccines.[45] The observed discrepancy became apparent as more affluent nations commenced the vaccination of their less vulnerable populations, whereas economically disadvantaged countries had challenges in obtaining vaccines, mainly for people at high risk, such as healthcare staff and fragile patients. The fundamental issue at hand was the proposal put forth by India and South Africa regarding the waiver of certain terms in the TRIPS Agreement. The primary objective of this proposal was to prevent the unequal distribution of vaccines and emphasize the importance of global cooperation in times of crisis, such as the COVID-19 pandemic.

Although wealthier nations may initially prioritize self-preservation over providing assistance to others, this inclination represents a short-term perspective. Disregarding the fundamental necessities of other nations might give rise to potential animosity and is not conducive to the pursuit of their long-term objectives.[46] The exclusive reliance on internal containment measures will not result in sustainable advantages since an extended global recuperation period following the epidemic hinders the elimination of trade barriers, hence undermining their own self-interests.

Expanding upon this line of argumentation, albeit from a humanitarian standpoint, the objective of patent waivers is to protect a maximum number of human lives and enhance worldwide resilience against the lethal COVID-19 virus. According to immunization data from lower-income nations, alternative strategies like the COVAX project, increased production for export to economically underdeveloped countries,

[44] Uwemedimo, E. (2023, August 29). *Keeping tabs on covid-19: Debate intensifies over covid-19 vaccine patent waiver*. Pharma IQ. https://www.pharma-iq.com/pre-clinical-discovery-and-development/articles/keeping-tabs-covid-19-debate-intensifies-covid-19-vaccine-patent-waiver
[45] Ibid.
[46] Ranjan, P. (2021, April 15). *The case for waiving intellectual property protection for covid-19 vaccines*. ORF. https://www.orfonline.org/research/the-case-for-waiving-intellectual-property-protection-for-covid-19-vaccines/

and the practice of voluntary licensing appear ineffective in adequately addressing the broader public health requirements.[47]. This argument prioritizes the inherent value of an individual's entitlement to vaccination, emphasizing its significance over the profit-oriented monopoly rights bestowed upon patent holders within the existing system that is the focus of the proposal.

In order to respond to concerns that the patent waiver does not automatically generate manufacturing capacity in countries that lack it, it is crucial to take into account that the removal of profit incentives resulting from exclusive patent rights may motivate countries with existing manufacturing capabilities to increase production and export to nations without such capacity. The patent waiver has the potential to facilitate discussions and result in more cost-effective pricing structures, in contrast to the elevated monopoly prices that would endure in its absence.[48]

In brief, the patent waiver presents one avenue for attaining a fair allocation of COVID-19 vaccines and guaranteeing worldwide availability through international cooperation, underscoring the significance of public health and human rights amidst the current difficulties. A multitude of perspectives surfaced with regard to the patent waiver system, both in the course of its implementation and subsequent to it. The waiver was perceived by certain individuals as an essential step in addressing the challenges faced by nations with limited capabilities to manufacture and distribute vaccines, since it attempted to alleviate the constraints imposed by the patent system's tight monopoly rights. On the other hand, there were individuals who strongly objected to this idea and campaigned for alternate strategies. One such strategy involved urging affluent nations to increase their manufacturing capabilities and exports in order to enhance accessibility for lower-income countries. However, it was widely agreed upon that the waiver, although a potentially positive measure in improving the accessibility of COVID-19 vaccines, was insufficient on its own to

[47] Erfani, P., Binagwaho, A., Jalloh, M. J., Yunus, M., Farmer, P., & Kerry, V. (2021, August 3). *Intellectual property waiver for covid-19 vaccines will advance global health equity*. The BMJ. https://www.bmj.com/content/374/bmj.n1837
[48] Ibid.

adequately tackle the problems of unequal distribution and limited access. These issues had significant negative consequences for public health.

B. Arguments against Patent Waivers

The opposition to patent waivers is primarily centered around the potential disruption of the patent system's underlying principles, which are designed to incentivize innovation and protect the economic rights of patent holders.[49] Critics argue that removing these protections for COVID-19 vaccines could discourage future investment in research and development (R&D), as companies rely on patents to recover the high costs associated with bringing new treatments to market. Without the assurance of exclusive rights, pharmaceutical companies may be less motivated to invest in future innovations, particularly in the face of a public health emergency like the COVID-19 pandemic. Additionally, opponents express concern that the temporary waiver might set a dangerous precedent, undermining global intellectual property protections and creating uncertainty for future investments in health-related technologies.

Another issue raised by critics is the complexity of implementing the waiver, especially in terms of regulatory oversight and the capacity to produce vaccines in low- and middle-income countries.[50] There is also concern about ensuring that safety standards and quality controls are maintained when manufacturing processes are expanded rapidly. Critics argue that without robust safeguards in place, the waiver could lead to the production of substandard vaccines that may compromise global health efforts.

Alternative solutions, such as making better use of existing provisions under the TRIPS Agreement, like compulsory licensing, have been proposed. Compulsory licensing would allow governments to grant licenses to third-party manufacturers in emergency situations, thus addressing public health needs without completely

[49] Frederick M. Abbott, *The TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, 5 WIPO J. 65 (2013)
[50] Thomas J. Bollyky & Chad P. Bown, *The Tragedy of Vaccine Nationalism: Only Cooperation Can End the Pandemic*, Foreign Affs., Sept./Oct. 2020, at 96.

dismantling the patent system. Another approach is voluntary licensing, exemplified by the COVID-19 Technology Access Pool (C-TAP), though critics note that this has proven insufficient to ensure widespread access to vaccines.[51]

Despite these alternatives, the challenges posed by the pandemic have revealed the limitations of existing mechanisms.[52] The patent waiver remains a contentious but necessary option for addressing the scale of vaccine inequality, especially in low-income countries. However, it raises broader questions about balancing public health priorities with the need to protect intellectual property rights and ensure continued innovation in the pharmaceutical sector.

XI. CONCLUSION AND SUGGESTIONS: ASSESSING THE EFFICIENCY OF PROPOSED PATENT WAIVER BASED ON ITS OBJECTIVE

When considering this matter, it is crucial to do a thorough assessment of the need and effectiveness of the patent waiver that has been granted in relation to COVID-19 vaccinations. This assessment focuses on the delicate equilibrium of interests that aims to attain a shared goal—a future that is both secure and sustainable[53]. At one extreme of the continuum, there is an undeniable and urgent need to protect and maintain the well-being of individuals in light of the complex and diverse obstacles presented by the COVID-19 epidemic. Conversely, the contention revolves around the economic advancement of prosperous nations. The ethical choice is to prioritize the public health and overall well-being of the global population over the financial benefits of pharmaceutical companies or even entire nations.[54]

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[51] World Trade Organization, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, WTO Doc. IP/C/W/669 (Oct. 2, 2020).

[52] Ruth Okediji, *Innovation and Technology Transfer to Address Climate Change: Lessons from the Global Debate on Intellectual Property and Public Health*, 15 Int'l J. Intell. Prop. Mgmt. 1 (2022).

[53] Latika Choudhary and Hardik Daga, Patent Waiver on Covid Vaccine: Access for all or Global Supply Crisis?. Journal of Intellectual Property Rights Vol 27, November 2022, pp 420-426 DOI: 10.56042/jipr.v27i6.62868

[54]. Erfani, P., Binagwaho, A., Jalloh, M. J., Yunus, M., Farmer, P., & Kerry, V. (2021, August 3). *Intellectual property waiver for covid-19 vaccines will advance global health equity*. The BMJ. https://www.bmj.com/content/374/bmj.n1837

Moreover, the empirical information about the practical application of the patent system does not present a strong case for its substantial promotion of innovation. In the present era, there is a notable interconnection between political economics and the ability of larger firms to amass a higher quantity of patents.[55] The correlation between a stronger patent system and a proportionate increase in innovation is not necessarily direct; rather, it primarily manifests in the form of a greater count of patents registered within a specific country. This statement highlights the rationale behind the patent waiver. In situations where one could contend that innovation plays a crucial role in combating the COVID-19 pandemic, the primary function of the patent system in promoting economic interests rather than stimulating innovation presents a persuasive justification for granting the waiver, with a primary emphasis on public health.

The extended timeframe of 20 months necessary for the World Trade Organization (WTO) to approve the waiver gives rise to relevant inquiries. Moreover, the limited extent of the waiver introduces intricacy to the investigation.[56] Lower- and middle-income countries effectively communicated the need to promptly and decisively confront the extensive consequences of COVID-19, particularly as its severity increased.[57] The extended duration of this timeframe provided patent-holding pharmaceutical companies with the chance to safeguard their interests to some extent, if not entirely. The approval of the waiver occurred after the significant containment of the epidemic, which may have potentially compromised its efficacy.[58]

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[55] Ellen 't Hoen, Brook K Baker, Katrina Perehudoff and Martin Khor, *Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 2001–2016* (World Health Organization 2018) https://apps.who.int/iris/handle/10665/272875 accessed 12 May 2025.

[56] Waiving intellectual property rights for covid-19 vaccines. (n.d.). https://researchbriefings.files.parliament.uk/documents/CBP-9417/CBP-9417.pdf

[57] Agbo O & Gwom S, 'The Global Patent Waiver for Covid-19 Vaccines: A Naïve Realism on Private Property Rights' (2021

[58] Gabriele, S. (2022, November 1). *What happened to the COVID-19 vaccine patent waiver? - bill of health.* Bill of Health - The blog of the Petrie-Flom Center at Harvard Law School. https://blog.petrieflom.law.harvard.edu/2022/11/08/what-happened-to- the-covid-19-vaccine-patent-waiver/

Concerns have been raised regarding the possible misuse of the patent waiver by larger corporations in moderately developed countries aiming to enhance their financial gains.[59] There were additional concerns over the oversight of manufacturing capacity and compliance with safety regulations for vaccinations, particularly in relation to the implications of lower costs. Nevertheless, these apprehensions can be efficiently addressed by implementing internal regulations and additional safeguards or processes, obviating the need for a postponement in the issuance of the patent waiver.

The arguments presented offer significant rationale for the adoption of a patent waiver as a means to address the proliferation of the COVID-19 pandemic, even if it requires deviating from the conventional patent framework. Although the patent waiver alone may not serve as a comprehensive solution for effectively controlling the epidemic, it undoubtedly represents a crucial advancement in guaranteeing the availability and affordability of COVID-19 preventive measures and treatments in countries with lower and moderate incomes.

A. Way Forward: Actionable Recommendations for Policymakers

In moving forward, policymakers must prioritize the creation of a robust, flexible framework that balances public health needs with economic considerations. A comprehensive review of patent waiver systems should be conducted, focusing on their practical implications and the long-term effects on innovation, particularly in health-related sectors. Policymakers should also ensure that safeguards are in place to prevent misuse of such waivers by large corporations, while fostering international cooperation to address gaps in vaccine distribution and manufacturing capabilities. Additionally, continued collaboration between governments, international organizations, and the private sector is essential to establish regulatory frameworks that support equitable access to medical technologies during global health crises.

[59] Lrire. (2023, January 27). *The WTO waiver on covid-19 vaccine patents*. UCLA Law Review. https://www.uclalawreview.org/the-wto-waiver-on-covid-19-vaccine-patents/

B. Post-COVID-19: The Current Status

Since the WTO approved a limited patent waiver for COVID-19 vaccines in June 2022, global circumstances have evolved considerably. The pandemic has since transitioned from a global emergency to an endemic phase, with the World Health Organization formally declaring the end of COVID-19 as a public health emergency of international concern in May 2023. This shift has altered the urgency surrounding the waiver, but it has not diminished the importance of understanding its implications for future global health crises.

Following the waiver's adoption, debates continued over whether to expand its scope to include diagnostics and therapeutics. Although developing countries like South Africa and India pressed for this extension, WTO members have not reached a consensus, and the deadline for a decision was repeatedly postponed. As of early 2025, no agreement has been finalized, highlighting persistent divisions between developed and developing countries on intellectual property and equitable access to medical technologies.

Meanwhile, global vaccine access has improved due to increased production, falling demand, and diversified procurement strategies. However, structural inequalities in access to medical tools—particularly in low- and middle-income countries—remain evident. Platforms like the COVID-19 Technology Access Pool (C-TAP) and initiatives for voluntary licensing saw limited participation from major pharmaceutical companies, underscoring challenges in relying solely on goodwill for technology sharing.

Although COVID-19 no longer dominates global health agendas, the debates sparked by the waiver have carried over into discussions on pandemic preparedness and the reform of intellectual property norms. The WTO's waiver decision, albeit limited and delayed, set a precedent for revisiting TRIPS flexibilities in public health emergencies. Going forward, lessons drawn from this episode may inform negotiations on a pandemic treaty and shape more resilient frameworks for global access to life-saving innovations.

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XII. REFERENCES / BIBLIOGRAPHY

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